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Form P	TO-144	9 (modified)		Atty. Docket No.:		Serial No.:			
				CHEP:015US 10/561,034					
List of P	atents an	d Publications for A	Applicant's	Applicant: Laurence CHRISTA et al.					
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	C4			ength ALF-5755 activity Report of Dr. Didier Sa					
	C5	hepatocytes," INSERM, Research Report of Dr. Didier Samuel, M.D., Ph.D., pages 1-7. "Evaluation Report, Research Unit: Physiopathogenesis and treatment of fulminant hepatitis							
	CS			n: Physiopamogenesis at th and Education Evalua					
		December 2008.				, ,,,,	r-o,		
	C6	"Guidance for indu	strv - For the s	submission of chemistry.	manufact	uring, and co	ntrols		
		information for a t	herapeutic reco	mbinant DNA-derived p	roduct or	a monoclonal	antibody		
		product for in vivo use," Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER), August 1996.							
	C7			cifications: test procedu					
	1	biotechnological/b	iological produ	cts," U.S. Department of	Health ar	ıa Human Se	rvices, Food		

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EXAMINER: /Zachary Howard' DATE CONSIDERED: 10/13/2010

EXAMINER: INITIAL IF REFERENCE CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP609, DRAW LINE THROUGH

CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

Biologics Evaluation and Research (CBER), pages 1-21, August 1999.

"Guideline for industry – Quality of biotechnological products: stability testing of

for Human Use (ICH), pages 1-10, July 1996.

and Biologics, Draft, April 10, 1985.

and Drug Administration, Center for Drug Evaluation and Research (CDER), and Center for

biotechnological/biological products," Expert Working Group (Quality) of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals

"Points to consider in the production and testing of new drugs and biologicals produced by recombinant DNA technology," Office of Biologics Research and Review - Center for Drugs

Receipt date: 08/17/2010

		Page 2 of 2			
Form PTO-1449 (modified)		Atty. Docket No.:	Serial No.:	۱	
		CHEP:015US	10/561,034		
List of Patents and Publications for	and Publications for Applicant's Applicant:				
		Laurence CHRISTA	et al.		
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2		Patent Documents	Other Art		
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Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

Exam. Init.	Ref. Des.	Citation				
	C10	"Production and quality control of medicinal products derived by recombinant DNA technology," European Agency for the Evaluation of Medicinal Products (EMEA), pages 205-2616, December 1994.				
	C11	"Quality of biotechnological products: stability testing of biotechnological/biological products," European Agency for the Evaluation of Medicinal Products (EMEA), pages 263-273, December 1995.				
	C12	"Use of transgenic animals in the manufacture of biological medicinal products for human use," European Agency for the Evaluation of Medicinal Products (EMEA), pages 287-294, December 1994.				
	C13	Christa et al., "High expression of the human hepatocarcinoma-intestine-pancreas/pancreatic-associated protein (HIP/PAP) gene in the mammary gland of lactating transgenic mice – Secretion into the milk and purification of the HIP/PAP lectin," Eur. J. Biochem., 267:1665-1671, 2000.				

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